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# 510(k) Summary

APR 21 2008

I. Applicant:

Cell Gen Therapeutics, LLC
17734 Preston Road
Suite 204
Dallas, TX 75252
Phone (214)914-2762
Fax (972)380-0999
Date 12/14/2007

II. Device name: Cell Gen Laser, model CG-4000
Common name: Infrared Lamp
Classification: Infrared Lamp (21 CFR 890-5500)
Product Code: ILY

III. Intended Use:

The model CG-4000 Cell Gen laser emits energy in the infrared spectrum to provide topical heating to elevate tissue temperature for temporary relief of muscle and joint pain, muscle spasm and stiffness associated with arthritis. It also increases blood circulation and relaxes muscle tissue.

IV. Predicate Device:

a. Neurolase150 – cleared under K032787 dated November 20, 2003

V. Device Description:

The Cell Gen CG-4000 laser is a non-invasive, diode laser system consisting of an enclosure which contains the control unit and a treatment probe connected by an optic fiber.

VI. Substantial Equivalency:

The CG-4000 and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices use infrared laser diodes to generate topical heating for temporary relief of muscle and joint pain. The overall safety and effectiveness of the CG-4000 is not affected by differences in design from the predicate devices.

VII. Testing:

Testing of the CG-4000 will include performance testing and electrical safety testing in accordance with all applicable standards for this type of medical device.

VIII. Conclusions:

In consideration of the testing and comparison to the predicate devices, the CG-4000 has similar function, performance, energy source and intended uses to these devices. This laser is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2008

Cell Gen Therapeutics, LLC
% Mr. Dick Rivera
President
17734 Preston Road, Suite 204
Dallas, Texas 75252

Re: K080084
Trade/Device Name: Cell Gen Laser, Model CG 4000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: March 24, 2008
Received: March 25, 2008

Dear Mr. Rivera:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K080084

Device Name: Cell Gen Laser, Model CG 4000

Indications For Use:

The model CG-4000 Cell Gen laser emits energy in the infrared spectrum to provide topical heating to elevate tissue temperature for temporary relief of muscle and joint pain, muscle spasm and stiffness associated with arthritis. It also increases blood circulation and relaxes muscle tissue.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices



510(k) Number K080084